IN THE CLAIMS:

Claim 1. (Currently Amended) A process for detecting or determining a C-peptide-containing impurity comprising human C-peptide, monkey C-peptide, or a mixture thereof, in a sample of recombinantly produced human insulin or a derivative thereof, by a non-radioactive assay, comprising the steps of:

(a) adding a C-peptide tracer to the sample;

(b) adding antibody specific for the C-peptide containing impurity to the sample;

(c) adding a C-peptide second antibody bead capable of capturing said antibody specific for the C-peptide containing impurity ~~having at least one label~~ to the sample; and

(d) detecting or determining the presence of the C-peptide-containing impurity in the sample,

wherein the process is performed at a pH of about 8.5 to about 9.0.

Claim 2. (Original) The process according to claim 1, wherein the C-peptide-containing impurity is C-peptide, preproinsulin or a derivative thereof, or a C-peptide containing insulin or a derivative thereof.

Claim 3. (Canceled)

Claim 4. (Canceled)

Claim 5. (Canceled)

Claim 6. (Previously Presented)The process according to claim 1, wherein the antibody

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specific for the C-peptide impurity additionally recognizes at least one compound selected from the group consisting of preproinsulin, reduced human insulin, alkylated human insulin, human insulin cleaved with endoproteinase, Lys(B3)-Glu(B29)-human insulin C-peptide, and Lys(B3)-Glu(B29)-human insulin preproinsulin.

Claim 7. (Previously Presented) The process according to claim 1, wherein the antibody specific for the C-peptide impurity recognizes both C-peptide and preproinsulin with nearly the same affinity.

Claim 8. (Previously Presented) The process according to claim 1, wherein the tracer is chemiluminescent.

Claim 9. (Previously Presented) The process according to claim 8, wherein the tracer comprises an acrdinium ester moiety.

Claim 10. (Previously Presented) The process according to claim 1, wherein the presence of about 1 mg/mL human insulin does not interfere with the binding of the antibody specific for the C-peptide impurity.

Claim 11. Previously Presented) The process according to claim 1, wherein the antibody specific for the C-peptide impurity is obtained by immunizing a mammal with a purified insulin C-peptide.

Claim 12. (Previously Presented) The process according to claim 11, wherein the mammal is a sheep.

Claim 13. (Previously Presented) The process according to claim 11, wherein the purified insulin C-peptide is monkey C-peptide.

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Claim 14. (Previously Presented) The process according to claim 11, wherein the purified insulin C-peptide is human C-peptide.

Claim 15. (Currently Amended) A process for detecting or determining a C-peptide-containing impurity comprising human C-peptide, monkey C-peptide, or a mixture thereof, in a sample of recombinantly produced human insulin or a derivative thereof, by a non-radioactive assay, comprising the steps of:

(a) adding a C-peptide tracer to the sample;

(b) adding antibody specific for the C-peptide containing impurity to the sample;

(c) adding a C-peptide second antibody bead capable of capturing said antibody specific for the C-peptide containing impurity ~~having at least one label~~ to the sample; and

(d) detecting or determining the presence of the C-peptide-containing impurity in the sample,

wherein:

(i) the presence of about 1 mg/ml human insulin does not interfere with the binding of the antibody specific for the C-peptide impurity; and

(ii) the process is performed at a pH of 8.5 to about 9.0.

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